

In the United States Court of Federal Claims
OFFICE OF SPECIAL MASTERS
No. 20-1931V

BRIAN CHEW,

Petitioner,

v.

SECRETARY OF HEALTH AND
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: April 10, 2024

Maximillian J. Muller, Muller Brazil, LLP, Dresher, PA, for Petitioner.

Margaret Armstrong, U.S. Department of Justice, Washington, DC, for Respondent.¹

RULING ON ENTITLEMENT – SPECIAL PROCESSING UNIT²

On December 21, 2020, Brian Chew filed a Petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*³ (the “Vaccine Act”), alleging that he suffered a shoulder injury related to vaccine administration (“SIRVA”) as a result of a tetanus-diphtheria-acellular pertussis (“Tdap”) vaccine administered to him on May 18, 2019. Petition (ECF No. 1). The case was assigned to the Special Processing Unit of the Office of Special Masters (the “SPU”).

¹ Respondent was represented by Dhairya Jani initially and until September 2022, then by RONALDA KOSH – including on the Rule 4(c) Report and briefing – until March 2024. See Notices of Appearance (ECF Nos. 15, 30, 48).

² Because this Ruling contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims' website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

³ National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

For the foregoing reasons, I find that Petitioner has preponderantly established the onset of shoulder pain within 48 hours of vaccination; that the finding of a rotator cuff tear does not defeat his SIRVA claim; and that he suffered reduced range of motion (“ROM”). Based on the lack of other objection from Respondent as to other Table elements, and an independent review of the record, Petitioner has established entitlement.

I. Procedural History

After Petitioner filed the Petition and some initial evidence, the matter was assigned to SPU in August 2021. ECF No. 13. In November 2021, Respondent requested further evidence of Petitioner’s medical history for the three years pre-vaccination. Status Report (ECF No. 17); see *also* PAR Questionnaire (ECF No. 6) (listing only post-vaccination medical providers). In response, Petitioner filed a supplemental affidavit, insurance statements, and additional medical records. The parties engaged in settlement discussions but ultimately reached an impasse. Status Reports (ECF Nos. 28, 31 – 35).

Thus, on May 9, 2023, Respondent filed his Rule 4(c) Report opposing compensation for a Table SIRVA. Rule 4(c) Report (ECF No. 36); see *also* Scheduling Order (ECF No. 38) (memorializing status conference); Joint Status Report (ECF No. 39) (confirming that Petitioner would make a further effort). Petitioner filed additional medical records thereafter, and then Petitioner briefed his entitlement for a Table SIRVA. Brief, filed Oct. 30, 2023 (ECF No. 46). Respondent filed a Response on Dec. 15, 2023 (ECF No. 47). Petitioner did not file a Reply. The matter is now ripe for adjudication.

II. Authority

Before compensation can be awarded under the Vaccine Act, a petitioner must demonstrate, by a preponderance of evidence, all matters required under Section 11(c)(1), including the factual circumstances surrounding his claim. Section 13(a)(1)(A). In making this determination, the special master or court should consider the record as a whole. Section 13(a)(1). Petitioner’s allegations must be supported by medical records or by medical opinion. *Id.*

To resolve factual issues, the special master must weigh the evidence presented, which may include contemporaneous medical records and testimony. See *Burns v. Sec’y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993) (explaining that a special master must decide what weight to give evidence including oral testimony and contemporaneous medical records). Contemporaneous medical records are presumed to be accurate. See *Cucuras v. Sec’y of Health & Hum. Servs.*, 993 F.2d 1525, 1528 (Fed. Cir. 1993). To overcome the presumptive accuracy of medical records testimony, a

petitioner may present testimony which is “consistent, clear, cogent, and compelling.” *Sanchez v. Sec’y of Health & Hum. Servs.*, No. 11–685V, 2013 WL 1880825, at *3 (Fed. Cl. Spec. Mstr. Apr. 10, 2013) (citing *Blutstein v. Sec’y of Health & Hum. Servs.*, No. 90–2808V, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998)).

In addition to requirements concerning the vaccination received, the duration and severity of petitioner’s injury, and the lack of other award or settlement,⁴ a petitioner must establish that she suffered an injury meeting the Table criteria, in which case causation is presumed, or an injury shown to be caused-in-fact by the vaccination she received. Section 11(c)(1)(C).

The most recent version of the Table, which can be found at 42 C.F.R. § 100.3, identifies the vaccines covered under the Program, the corresponding injuries, and the time period in which the particular injuries must occur after vaccination. Section 14(a). Pursuant to the Vaccine Injury Table, a SIRVA is compensable if it manifests within 48 hours of the administration of a flu vaccine. 42 C.F. R. § 100.3(a)(XIV)(B). The criteria establishing a SIRVA under the accompanying QAI are as follows:

Shoulder injury related to vaccine administration (SIRVA). SIRVA manifests as shoulder pain and limited range of motion occurring after the administration of a vaccine intended for intramuscular administration in the upper arm. These symptoms are thought to occur as a result of unintended injection of vaccine antigen or trauma from the needle into and around the underlying bursa of the shoulder resulting in an inflammatory reaction. SIRVA is caused by an injury to the musculoskeletal structures of the shoulder (e.g., tendons, ligaments, bursae, etc.). SIRVA is not a neurological injury and abnormalities on neurological examination or nerve conduction studies (NCS) and/or electromyographic (EMG) studies would not support SIRVA as a diagnosis (even if the condition causing the neurological abnormality is not known). A vaccine recipient shall be considered to have suffered SIRVA if such recipient manifests all of the following:

(i) No history of pain, inflammation or dysfunction of the affected shoulder prior to intramuscular vaccine administration that would explain the alleged

⁴ In summary, a petitioner must establish that he received a vaccine covered by the Program, administered either in the United States and its territories or in another geographical area but qualifying for a limited exception; suffered the residual effects of his injury for more than six months, died from his injury, or underwent a surgical intervention during an inpatient hospitalization; and has not filed a civil suit or collected an award or settlement for her injury. See Section 11(c)(1)(A)(B)(D)(E).

signs, symptoms, examination findings, and/or diagnostic studies occurring after vaccine injection;

(ii) Pain occurs within the specified time frame;

(iii) Pain and reduced range of motion are limited to the shoulder in which the intramuscular vaccine was administered; and

(iv) No other condition or abnormality is present that would explain the patient's symptoms (e.g., NCS/EMG or clinical evidence of radiculopathy, brachial neuritis, mononeuropathies, or any other neuropathy).

42 C.F.R. § 100.3(c)(10) (2017).

III. Evidence

I have reviewed all submitted evidence including all medical records and affidavits, as well as the Petition, the Rule 4(c) Report, and both parties' briefing. The following section focuses on the evidence most relevant to the disputed criterion.

- Petitioner was born in 1974. With respect to his medical history for the three years prior to vaccination:
 - Petitioner was generally healthy, with no medical history related to the left shoulder and/or the musculoskeletal system. *See generally* Exs. 1, 4, 6, 7, 9, 11 – 15.
 - A primary care provider ("PCP"), Abeer S. Griggs, D.O., at Internal Medicine Institute of New Jersey, is referenced in the post-vaccination medical records. *See, e.g.*, Ex. 1 at 10; Ex. 5 at 28. However, that practice found no pre-vaccination dates of service for Petitioner. *See generally* Ex. 11.
 - Petitioner believes that he was an established but irregular patient of a different PCP, Angelo Chinnici, M.D. – but again, no relevant dates of service were found. Ex. 8 at ¶ 2; *see generally* Ex. 7.
- On May 18, 2019, Petitioner received the at-issue Tdap vaccination in his left shoulder/arm, during an urgent care visit for a leg laceration. Ex. 1 at 14 – 16.

- Forty-two (42) days later, on June 29, 2019, Petitioner sought a physical therapy (“PT”)⁵ initial evaluation for left shoulder pain since May 19, 2019. Ex. 2 at 2. Petitioner reported that “following” his Tdap vaccination, he had developed left shoulder pain and inability to move. *Id.* “Self-stretching” had improved his range of motion (“ROM”) but not his pain. *Id.* at 2, 5. The injury was “possible SIRVA?”. *Id.* at 5.
- On exam, his left shoulder’s active ROM was decreased⁶ - including flexion, scaption, and abduction to 150 degrees; extension to 40 degrees; functional external rotation to C7; functional internal rotation to T10; and neutral external rotation to 45 degrees. *Id.* at 3. Passive ROM was generally painful but within normal limits, except for limited external rotation to 60 degrees. *Id.* Strength was decreased, and impingement signs were positive. *Id.* at 3 – 4. The therapist recorded Petitioner’s problems as decreased ROM; decreased strength; scapula and glenohumeral joint instability; pain with movement, sleep, and dressing himself; and tenderness. *Id.* at 5. The therapist planned for Petitioner to attend two session of PT per week for eight weeks.
- Petitioner continued PT as planned, and a July 29, 2019, repeat physical examination of the left shoulder found improved active ROM – with flexion and scaption to 160 degrees; abduction to 170 degrees; extension to 60 degrees; functional external rotation to T2; functional internal rotation to T9; and neutral external rotation to 50 degrees. Ex. 2 at 41. The *passive* neutral external rotation measure was also improved to 90 degrees. *Id.* The therapist assessed that Petitioner was making “great progress,” and that “shoulder mobility has improved.” *Id.* at 43.
- Petitioner continued to attend PT thereafter, with his 15th session occurring on September 19, 2019. See *generally* Ex. 2 at 20 – 57.
- On September 24, 2019, Petitioner obtained an initial evaluation with a physical medicine and rehabilitation (“PM&R”) physician, who recorded his history of

⁵ Respondent notes that the PT records identify the “referring physician” as “Direct Access.” Response at n. 2. However, this does not indicate that Petitioner saw any medical provider prior to PT. Rather, the term “Direct Access” means that an individual can self-refer to PT without another medical provider’s prescription. See, e.g., American Physical Therapy Association of New Jersey, *Direct Access*, available at <https://aptanj.org/news/news.asp?id=477810> (posted Nov. 13, 2019, last accessed Apr. 4, 2024).

⁶ For adults, normal shoulder range of motion upon flexion ranges from 165 to 180 degrees; abduction from about 170 to 180 degrees; internal rotation from about 70 to 90 degrees; and external rotation from about 90 to 100 degrees. Cynthia C. Norkin & D. Joyce White, *Measurement of Joint Motion: A Guide to Goniometry* 72, 80, 84, 88, 5th ed. (2016).

“severe left shoulder pain with range of motion deficits” that had begun “after” receipt of the Tdap vaccine, and had improved with PT. Ex. 5 at 28. An exam found “full” passive and active flexion, abduction, and internal and external rotation,” and negative impingement signs. *Id.* at 29. The physician’s initial assessment was “left shoulder pain, SIRVA, rule out labral tear.”

- On September 27, 2019, the PM&R physician obtained MRI imaging to “evaluate for labral tear or subacromial bursitis.” Ex. 4 at 3. The MRI findings were: “Small subacute Hill-Sachs. Probable small bone bruise in the anterior inferior glenoid with mild non-displaced tearing at the anterior inferior labrum. Large internal partial tear at the insertion of supra- and infraspinatus tendons. No full-thickness rotator cuff tear. Mild subacromial subdeltoid bursitis.” *Id.*
- Petitioner attended PT on September 27 and October 2, 2019. Ex. 2 at 12 – 19.
- At an October 10, 2019, follow-up, the PM&R physician expressed uncertainty as to why a “standard” MRI had been obtained, because he had wanted arthrography to evaluate for “structural abnormalities.”⁷ Ex. 5 at 15. The physician otherwise proposed that the visualized rotator cuff tear was “likely the etiology of [Petitioner’s] symptoms.” *Id.* at 16. The bone bruising’s clinical significance, and the relevance of the vaccination, were “uncertain.” *Id.* The physician did not address the additional finding of bursitis. *Id.* Petitioner was instructed to continue PT and consult an orthopedic surgeon within the same practice group. *Id.*
- On October 15, 2019, Petitioner presented to the suggested orthopedic surgeon, who recorded a similar history of Petitioner’s left shoulder pain “beg[inning] after a tetanus shot,” while also noting that Petitioner was “involved in Cross-Fit, doing a lot of overhead presses and flies.” Ex. 5 at 12. An exam revealed normal ROM, decreased strength, mild tenderness, and mildly positive impingement signs. *Id.* at 13. The orthopedic surgeon did not believe that the vaccination had caused injury – reasoning: “There is no evidence of hematoma or abnormality of the deltoid. Axillary nerve function is normal.” *Id.* He focused on the rotator cuff tear, for which he recommended surgery. *Id.* He did not address the MRI finding of bursitis. *Id.*

⁷ Compared to a standard MRI, arthrography adds an injection of contrast “directly into the affected joint [which... allows for clearer images of the tendons, ligaments, and cartilage in the affected area.” Yale Medicine, *MRI Arthrography*, available at <https://www.yalemedicine.org/conditions/mri-arthrography-specialized-imaging-of-joints> (last accessed Apr. 4, 2024).

- Also on October 15, 2019, after attending his 18th PT session, Petitioner self-discharged while he considered surgery and/or an injection for his left shoulder. Ex. 2 at 6 – 11.
- On October 21, 2019, Petitioner obtained a second opinion at a different orthopedics practice. Ex. 10 at 4 – 6. He recounted that his left shoulder injury “began after” the Tdap shot, “improved with ice, rest, and [PT,]” but was still present. *Id.* at 4. An exam did not document ROM, but was positive for pain, weakness, and a positive impingement sign. *Id.* at 5. This second orthopedic surgeon’s assessment was similarly focused on the MRI findings of a rotator cuff tear, not bursitis. *Id.* at 5. He recommended a steroid injection (which was administered during the encounter) and more PT before any resort to surgery. Ex. 10 at 6; see *also* Ex. 5 at 8 (October 22, 2019, record by the first orthopedist, memorializing Petitioner’s plan to defer surgery); *accord* Ex. 6 at 2 (December 10, 2019, PCP note).
- Petitioner attended formal PT regularly for nearly three months more. Ex. 2 at 59 – 82. At his 26th session on January 13, 2020, the therapist assessed that Petitioner had made “great progress... his ROM and strength [are] now WFL [within functional limits]... has returned to the gym and has no limitations, but is careful with how much overhead lifting he performs... pain levels are 2/10 at worst... has been performing HEP regularly... he will be dc [discharged] from PT.” *Id.* at 79. There are no further records.
- I have also reviewed Petitioner’s affidavit prepared in December 2021, which includes his recollections of being in “good health” prior to the May 2019 vaccination; developing pain in the vaccinated left shoulder “within a few hours” thereafter; finding internet reports of “exactly what [he] was experiencing”; and that his longtime exercise regimen “had nothing to do” with his shoulder injury. See *generally* Ex. 8.

IV. Analysis

After a review of the entire record, I find that a preponderance of the evidence demonstrates that Petitioner has established a Table SIRVA, despite Respondent’s objections.

Respondent first contends that the Table onset requirement, at 42 C.F.R. §§ 100.3(a) and (c)(10)(ii), cannot be met because Petitioner conducted internet research on his injury and discovered others’ reports of vaccine injuries *before* presenting for medical attention 42 days post-vaccination. Respondent also maintains that the medical

records are insufficiently vague to support a finding of onset specifically within 48 hours. Rule 4(c) Report at 6; Response at 7 – 8. But the medical records consistently relate onset close in time to the vaccination, and are supplemented by Petitioner’s affidavit. There is no evidence that Petitioner’s shoulder pain began within any time period *beyond* 48 hours post-vaccination, or after any other precipitating event. And Petitioner cites extensive caselaw supporting the well-recognized proposition that treatment delays are not dispositive, especially because it is common for SIRVA petitioners to initially believe that post-vaccination shoulder pain will resolve on its own. Brief at 7 – 8 (internal citations omitted).⁸

Respondent’s second contention is that the MRI imaging and physicians’ assessments of a rotator cuff tear are “not consistent with a SIRVA.” Rule 4(c) Report at 6; Response at 8 – 9, presumably raising an objection to 42 C.F.R. § 100.3(c)(iv). Petitioner argues that this objection is vague and not supported by any medical opinion, and that the additional finding of bursitis confirms that he suffered a new musculoskeletal injury consistent with SIRVA. Brief at 8.

Evidence of the existence of a rotator cuff tear does not “*per se* preclude a finding that a Table SIRVA exists.” *Lang v. Sec’y of Health & Hum. Servs.*, No. 17-0995V, 2020 WL 7873272, at *13 (Fed. Cl. Spec. Mstr. Dec. 11, 2020) (noting an HHS-CDC joint study which found that rotator cuff tears were present in approximately 40% of a cohort of compensated SIRVA cases); *Grossmann v. Sec’y of Health & Hum. Servs.*, No. 18-0013V, 2022 WL 779666, at *17 (Fed. Cl. Spec. Mstr. Feb. 15, 2022) (citing the Atanasoff article relied upon in creating the SIRVA QAI, for the proposition that “MRI findings... such as rotator cuff tears, may have been present prior to vaccination and became symptomatic as a result of vaccination-associated synovial inflammation”); accord 42 C.F.R. § 100.3(c) (describing SIRVA as “an inflammatory reaction” within the musculoskeletal system of the shoulder); 42 C.F.R. § 100.3(c)(iv) (specifying that evidence of a *neurological* condition or abnormality can defeat a SIRVA claim). The key question is “whether Petitioner’s own clinical history indicates that [his] shoulder pathology wholly explains [his] symptoms *independent* of vaccination.” *Lang*, 2020 WL 7873272, at *13 (emphasis added).

⁸ It is conceivable that a Petitioner could misreport onset purposefully, in order to “fit” an alleged SIRVA into the Table timeframe. But to reach such a finding, I would need more corroborative evidence of the purported misstatement than has been provided here – and it would also be somewhat likely in such a case that other record proof (for example, the nature or extent of the pain) would undermine the claim.

Here, the record evidence supports the conclusion that Mr. Chew was healthy and active with no complaints of left shoulder pain or dysfunction, notwithstanding the possibility of an undetected rotator cuff tear prior to his vaccination.⁹ The bursitis finding is also consistent with SIRVA, even if it was not emphasized by the treating providers. Brief at 8 – 9. Thus, 42 C.F.R. § 100.3(c)(iv) is satisfied.

Respondent's third and final contention is that Petitioner "never" suffered reduced ROM. Response at 9 (citing Exs. 5, 6, 10); see also *Bolick v. Sec'y of Health & Hum. Servs.*, No. 20-0893V, 2024 WL 1160065, at *6 (Fed. Cl. Spec. Mstr. Oct. 19, 2023) (confirming that a Table SIRVA claim *does* require preponderant evidence of reduced ROM). But Respondent's position does not acknowledge Ex. 2 – the PT records, which are both the earliest post-vaccination records, and contain the most specific measures of ROM. Those records reflect that despite Petitioner's "self-stretching," at 42 days post-vaccination, on June 29, 2019, he did in fact display reduced active ROM on several measures and reduced passive neutral external rotation. Ex. 2 at 3. Admittedly, one month later (at his 6th PT session) those ROM measures had improved. *Id.* at 41. But then later medical records contain Petitioner's consistent history that his ROM decreased, even if it improved with PT. See, e.g., Ex. 2 at 11, 79; Ex. 5 at 12, 28. This evidence is sufficient for a Table SIRVA – ROM limitations must *exist*, but the Table does not require a showing that they continuously *persist*, and at the same level, any more than SIRVA claimants must prove pain remains at the same level for the entirety of the treatment course.

Conclusion and Scheduling Order

Based on a full review of the record and the lack of any further objections from Respondent, I find that Petitioner has established entitlement to compensation for a Table SIRVA. The case shall now proceed to the damages phase.

Prior filings indicate that the parties had reached an impasse on an appropriate award for Petitioner's pain and suffering, although any previously-expressed demand might have included past medical expenses. See, e.g., Status Report (ECF No. 26) at 1; Brief (ECF No. 46) at 1. The parties shall now resume their discussions of the appropriate pain and suffering award – recognizing that while Petitioner's entitlement is no longer in dispute, his formal treatment course was somewhat conservative and concluded less than

⁹ I also find that the evidentiary record is sufficiently complete based on Petitioner's repeated efforts to obtain all medical records from three years prior to the date of vaccination; his production of health insurance and benefits statements; and the absence of further requests from Respondent.

eight months post-vaccination,¹⁰ and my review of the evidence to date has not identified any unique or compelling circumstances that would support a particularly large pain and suffering award.

Accordingly, by no later than Friday, May 24, 2024, Petitioner shall file a Status Report updating on the parties' efforts to informally resolve damages. The status report shall include confirmation of whether any Medicaid lien exists, and if so, the date by which Petitioner anticipates providing Respondent a letter from the appropriate state agency verifying the amount of the lien. If an informal resolution cannot be reached, the parties shall jointly propose a schedule for briefing damages.

IT IS SO ORDERED.

s/Brian H. Corcoran

Brian H. Corcoran
Chief Special Master

¹⁰ *Contra* Ex. 8 at ¶ 9 (Petitioner's characterization that the SIRVA "took the better part of a year to resolve itself").